

Remarks

Claims 1-17 are pending in the subject application. By this Amendment, Applicants have canceled claims 1-17 and added new claims 18-37. Support for the new claims can be found throughout the subject specification, including, for example, at page 3, lines 3-5; page 3, lines 18-26; and page 4, lines 20-33, and in the claims as originally filed in the subject application and in the parent application (Serial No. 09/622,804). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 18-37 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 12 and 13 are rejected under 35 USC §101 on the grounds the claimed invention is directed to non-statutory subject matter. By this Amendment, Applicants have canceled claims 12 and 13, thereby rendering this rejection moot. Applicants note that new claims 18-24 recite that the nucleic acid molecule is isolated. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §101 is respectfully requested.

Claims 12-15 are rejected under 35 USC §112, second paragraph, as indefinite. Applicants respectfully assert that the claims as filed are definite. However, by this Amendment, Applicants have canceled claims 12-15, thereby rendering this rejection moot. Applicants note that the new claims presented in this Amendment recite that the extracellular domain of the protein binds biotin, in accordance with the Examiner's helpful suggestion. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 12-15 are rejected under 35 USC §102(b) as anticipated by Cantor *et al.* (WO 87/05026). The Examiner asserts that the Cantor *et al.* publication teaches a fusion protein (and nucleic acid encoding the same) comprising streptavidin and human LDL receptor and that the LDL receptor comprises a membrane spanning domain and intracellular domain and the streptavidin portion of the protein is in the extracellular domain of the fusion protein. Applicants respectfully traverse this ground of rejection.

Applicants respectfully assert that the Cantor *et al.* publication does not teach or suggest Applicants' claimed invention. The Cantor *et al.* publication does not teach or suggest a fusion protein comprising the membrane spanning domain of an endocytotic receptor that is a scavenger receptor class A. Nor does the Cantor *et al.* publication teach or suggest a nucleic acid that

comprises nucleotides 1071-2270 of SEQ ID NO.1 or a protein that comprises the amino acid sequence shown in SEQ ID NO. 2.

As noted above, the Cantor *et al.* publication describes the preparation of various fusion proteins with a streptavidin portion; however, the streptavidin portion is included to aid later in protein purification. In the purification method, a protein of interest is fused to a streptavidin, cultured (*in vitro* or *in vivo*) and then purified using the strong biotin-binding activity of streptavidin. Although the Cantor *et al.* publication discloses a fusion protein comprising a human LDL receptor, this is in an example showing the utility of the purification method, and there is no teaching or suggestion of any therapeutic benefit or application for the expressed fusion protein. In contrast, the claimed invention is based on the realization that biotinylated molecules can be targeted to particular sites *in vivo*, by localizing biotin-binding activity at the cellular target site. This is achieved by expressing the fusion protein *in situ*. Thus, Cantor *et al.* do not teach or suggest a medicament for therapeutic use that comprises a nucleic acid molecule of the present invention. Moreover, there is no teaching or suggestion in the Cantor *et al.* publication of a medicament that comprises a nucleic acid of the invention in a complex with a liposome, *etc.* for therapeutic administration to a patient or animal.

As the Examiner is aware, in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). Applicants respectfully assert that the Cantor *et al.* publication does not teach or suggest each and every element of every claim of the subject application. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(b) is respectfully requested.

Claims 12-15 are objected to because they depend on non-elected claim 1. Claim 15 is objected to under 37 CFR §1.75(c) as being un improper form because it depends upon both claims 1 and 16. As noted above, claims 12-15 have been canceled by this Amendment. In addition, the new claims presented herein have been drafted to avoid dependence on non-elected or canceled claims. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

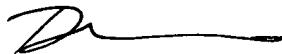
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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